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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,564	08/28/2006	Peter Richardson	13425-170US1	4551

26161 7590 05/14/2007
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EXAMINER	
CRANE, LAWRENCE E	
ART UNIT	**PAPER NUMBER**
1623	

MAIL DATE	DELIVERY MODE
05/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/537,564	RICHARDSON, PETER	
	Examiner	Art Unit	
	L. E. Crane	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *June 3, 2005 (preliminary amendment)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

The Abstract of the Disclosure is objected to because is does not meet the requirement of the MPEP for US application. Correction is required. See MPEP 608.01(b).

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts, compounds or compositions, the general nature of the compound or composition should be given as well as its use, e.g., "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary. Complete revision of the content of the abstract is required on a separate sheet.

The instant Abstract has not been presented in US format and is excessively brief, and specifically fails to include the structure of the active ingredient. Appropriate correction is respectfully requested.

Claims **1-10** have been cancelled, claims **14-15, 17-21 23-27 and 29-31** have been amended, the disclosure has been amended at page 1, and no new claims have been added as per the preliminary amendment filed June 3, 2005. No Information Disclosure Statements (IDSs) have been filed as of the date of this Office action.

Claims **11-31** remain in the case.

Note to applicant: when a rejection refers to a claim **X** at line y, the line number "y" is determined from the claim as previously submitted by applicant in the most recent response including ~~lines deleted by line through~~.

Claims **11-31** are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant disclosure fails to provide adequate written description of the "prevention" of pain (see claims **11, 15 and 18**) associated with any disease condition by the administration of

the single compound (2-methoxyadenosine) listed herein as an active ingredient. In addition, there is no written description supporting adequately the co-administration of 2-methoxyadenosine with any other substance known to act as an analgesic. And the instant disclosure fails to provide any description of the effective treatment of pain associated with any cancer including pancreatic cancer or brain cancer, any auto-immune disease, epilepsy, neurodegeneration including Alzheimer's Disease, HIV, AIDS, ARC, silicosis, myasthenia gravis, Crohn's Disease, bacterial meningitis, and nearly all of the other diseases listed generically or specifically in any of claims **11, 15 and 18**.

Claims **11-31** are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabled for the treatment of inflammation and hypertension, does not reasonably provide enablement for the treatment of any other disease condition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The fundamental issue here is whether practicing the full scope of the instant invention is possible without undue experimentation. As provided for in *In re Wands* (858 F.2d 731, 737; 8 USPQ 2d 1400, 1404 (Fed Cir. 1988) the minimum factors to be considered in determination of whether a conclusion of "undue experimentation" is appropriate are as follows:

A. The breadth of the claims: The instant claims are directed to the treatment of pain associated with a vast array of specifically named, and generically defined, disease conditions wherein the instant disclosure fails to define how to effective treat the vast majority thereof. The claims are therefore deemed to be excessively broad in scope.

B. The nature of the invention: The invention defined by the listed claims is directed to the treatment of a vast array of diseases by the administration of a 2-methoxyadenosine to a host in need of treatment.

C. The state of the prior art: The prior art identifies the claimed active ingredients but does not identify the instant claimed pharmacological activity.

D. The level of one of ordinary skill: One of ordinary skill would be expected to be familiar with the details of the medicinal treatment of the diseases listed in claims **11, 15 and**

18, a literal impossibility because no one practitioner, or even a dozen practitioners combined, would be able to meet this requirement.

E. The level of predictability in the art: In view of the absence of teachings herein and in the prior art to provide relevant guidance directed to treatment of each of the vast array of disease conditions listed in claims **11, 15 and 18**, the predictability of the art is deemed to be very low.

F. The amount of direction provided by the applicant: The instant disclosure, as noted above, only supplies two and one-half pages of guidance and an indication of how to treat pain associated with only a few model test hosts wherein the pain has been induced artificially.

G. The existence of working examples: The existence and the content of examples is described in the previous paragraph.

H. The quantity of experimentation needed to make or use the invention based on the content of the disclosure is deemed to be excessive because the bare minimum of examples in the instant disclosure at pages 7-9 is entirely inadequate to provide the guidance necessary to practice the instant claimed methods in the treatment of pain predictably in the vast majority of the disease conditions listed in claims **11, 15 and 18**.

Claims **15** and**18** are objected to because of the following informalities:

In claim **15** at line 3, the term "pelvicpain" is grammatically incorrect because the noted term should be two separate words.

In claim **18** at line 12, the term "colitis and pyresis" is grammatically incorrect. In view of what appears to be a list of alternative disease conditions, did applicant intend the term to read -- colitis, pyresis --?

In claim **18** at line 13, the term "or adverse effects" appears to be grammatically incorrect. Did applicant intend the term to read -- the adverse effects --?

Appropriate correction is required.

Claims **14, 18 and 27** are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim **14** the term "disease that causes damage to sensory neurons" renders the claim incomplete because the particular diseases implied by said term have not been defined in the claim.

In claim **18** at line 4, the term "arthritic conditions" has not been further defined in the claim, thereby rendering the claim incomplete.

In claim **27** at line1 the term -- further comprising -- or the like is missing as providing a proper basis for expansion of the scope of the subject matter of claim **11**. For this reason claim **27** lacks proper antecedent basis in claim **11**.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel,* 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam,* 686 F. 2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir 1985); and *In re Goodman,* 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. §1.78(d).

Effective January 1, 1994, a registered attorney or agent or record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. §3.73(b).

Claims **11-31** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***16-33*** of copending Application No. **10/547,455**. Although the conflicting claims are not identical, they are not patentably distinct

from each other because the methods of treatment both appear to include or imply the treatment of pain and the alleged active ingredients (2-alkoxyadenosines and their 3'-deoxy analogues) are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **11-31** are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims ***13-24*** of copending Application No. **10/547,454**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods of treatment both appear to include or imply the treatment of pain and the alleged active ingredients (2-alkoxyadenosines and their 3'-deoxy analogues) are directed to substantially overlapping subject matter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims **11-31** of this application conflict with ***13-24*** of copending Application No. **10/547,454** and ***16-33*** of copending Application No. **10/547,455**. 37 C.F.R. §1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP §822.

The following is a quotation of 35 U.S.C. §103(**a**) which forms the basis for all obviousness rejections set forth in this Office action:

> "A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made."

Claims **11-31** are rejected under 35 U.S.C. §103(**a**) as being unpatentable over **Fukunaga '290** (PTO-892 ref. **C**) in view of **Fukunaga et al. '650** (PTO-892 ref. **A**) and further in view of **Ueeda et al.** (PTO-892 ref. **R**).

The instant claims are directed to methods of treatment wherein 2-methoxyadenosine is administered to treat pain associated with a disease condition selected from a vast array of possibilities.

Fukunaga '290 at column 4, lines 23-54 discloses that carefully controlled continuous administration of adenosine or analogues thereof can cause relief from pain and inhibition of "stress" wherein the symptoms of "stress" are also commonly associated with inflammation. The **'290** reference also teaches that adenosine or its analogues can be administered at rates that avoid hypotension while producing the desired degree of pain relief.

The **Fukunaga '290** reference does not expressly disclose 2-methoxyadenosines as an active ingredient in any method of treatment.

Fukunaga et al. '650 discloses at column 18, lines 48-61 that adenosine administered with sufficient amount of catecholamine modulates the undesirable side effects associated with administration of the anesthetic fentanyl. In addition at column 23, lines 30-47 this reference discloses in general that large dosages of adenosine in combination with a catecholamine are effective in minimizing the damage from a number of disease conditions including ischemia. Subsequent examples at columns 23-24 teach that adenosine may be substituted by a number of different adenosine analogues with similar outcomes. The antihypertensive, antinociceptive (pain inhibiting), and the anti-inflammatory effects of adenosine are notoriously well known in the art as disclosed in the **'650** reference at columns 1-4.

Fukunaga et al. '650 does not expressly disclose 2-methoxyadenosine as an active ingredient in any method of treatment.

Ueeda et al. discloses at page 1353 that the compound 2-ethoxyadenosine has binding constants at adenosine receptors that vary very little from the binding constants for adenosine, for R-PIA and for NECA, a teaching supporting the conclusion that substitution of an adenosine analog for adenosine would be expected to produce a similar effect, including the analgesic effect on pain.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to substitute compounds very closely analogous to the compounds disclosed by **Ueeda et al.** into the methods disclosed by the **Fukunaga** references because the

Fukunaga references explicitly teach the pharmacological equivalence of adenosine and adenosine analogues.

One having ordinary skill in the art would have been motivated to combine these references because all three references are directed to overlapping disclosures of the medicinal administration of adenosine and analogues of adenosine, including one compound defined herein as an active ingredient, to treat various disease conditions including pain, inflammation and hypertension.

Therefore, the instant claimed methods of administration of 2-methoxyadenosine to treat a variety of disease conditions including pain, inflammation and hypertension would have been obvious to one of ordinary skill in the art having the above cited references before him at the time the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. §1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(f) or (g) prior art under 35 U.S.C. §103(a).

Papers related to this application may be submitted to Group 1600 via facsimile transmission (FAX). The transmission of such papers must conform with the notice published in the Official Gazette (1096 OG 30, November 15, 1989). The telephone number to FAX (unofficially) directly to Examiner's computer is 571-273-0651. The telephone number for sending an Official FAX to the PTO is 571-273-8300.

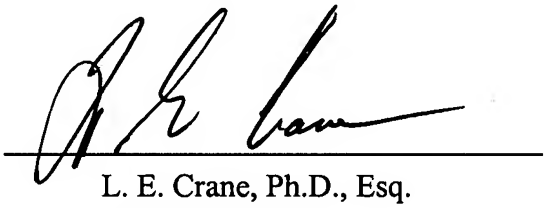
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner L. E. Crane whose telephone number is **571-272-0651**. The examiner can normally be reached between 9:30 AM and 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. S. Anna Jiang, can be reached at **571-272-0627**.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is **571-272-1600**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status Information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see < http://pair-direct.uspto.gov >. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

LECrane:lec
05/10/2007



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